

DOCKET NO.: IBIS-0012

PATENT

48. The oligonucleotide of claim 36 wherein said structural motif is identified by performing self complementarity comparison, alignment and covariance analysis, secondary structure prediction, or a combination thereof.

49. The oligonucleotide of claim 37 wherein said set of descriptor elements is constructed using a descriptor database.

50. The oligonucleotide of claim 38 wherein said other nucleic acids having secondary structures corresponding to said descriptor elements are identified by searching at least one database, performing clustering and analysis, searching for orthologs, or a combination thereof.--

REMARKS

Claims 1-34 were originally filed in the present application. Claims 1-25 and 30-34 have been cancelled herein without prejudice to their presentation in another application as being drawn to non-elected subject matter. Claim 26 has been amended and new claims 35-50 have been added. Upon entry of the present invention, claims 26-29 and 35-50 will be pending in the present application.

As a preliminary matter, the Office Action asserts that a proposed drawing correction is required in response to the present Office Action. Form PTO-948 indicates that: 1) the margins for many of the drawings are not acceptable, 2) the lines, numbers and letters for Figure 35 are not clear, 3) the numbers and reference characters for Figure 35 are not plain and legible, and 4) the numbers, letters and reference characters for Figure 3 are not the appropriate height. Applicants respectfully point out that these deficiencies are not required to be corrected immediately in order to permit a reasonable examination of the application. See M.P.E.P. 608.02(a). Indeed, a reasonable examination of the application has, in fact, been carried out. Further, 37 C.F.R. §1.85 allows Applicants to provide formal drawings after a Notice of Allowance has been received. Formal drawings correcting the deficiencies noted in Form PTO 948 will be filed upon an indication of allowable subject matter. Applicants submit that this is a complete response.

New claims 35-50 have been added, support for which can be found throughout the specification.

New pages 1-96 containing the Sequence Listing are provided to comply with the Sequence Rules set forth in 37 CFR § 1.821-1.825. A Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures mailed along with the present Office Action indicated that the application failed to comply with rules set forth in 37 CFR 1.821-1.825. The enclosed new pages 1-96 contain the Sequence Listing, formatted under the new rules for submitting Sequence Listings, support for which can be found throughout the application as originally filed. No new matter has been added. In addition, please find enclosed herewith a copy of the Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures, a Response to Notice To Comply With Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosure, a Statement to Support Filing and Submission of DNA/Amino Acid Sequences in Accordance with 37 CFR §§ 1.821 through 1.825, and a computer readable form (CRF). Further, the contents of the paper copy of the Sequence Listing and computer readable copy of the Sequence Listing, submitted in accordance with 37 CFR §1.821(c) and (e), are the same.

I. Double Patenting Rejection

Claims 26-29 are provisionally rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claims 26-29 of co-pending application Serial No. 09/076,440. Since claims 26-29 of co-pending application Serial No. 09/076,440 are not pending and have, in fact, been canceled, Applicants request that this rejection be withdrawn.

II. The Claimed Invention Is Not Anticipated

Claim 26 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Harrison *et al.*, *Biochim. Biophys. Acta*, 1996, 1275, 161-203 (hereinafter, the "Harrison reference"). The Office Action asserts that page 186 and Figure 12 of the Harrison reference depicts a nucleotide sequence of the iron response element that controls translation in response to iron. Applicants have

amended claim 26 to preclude the iron response element support for which can be found at, for example, page 29, lines 27-28 and Example 1 of the specification, wherein Applicants teach that the novel methods were, in fact, used to identify a known regulatory region of the iron response element. Accordingly, Applicants respectfully request that the rejection of claim 26 under 35 U.S.C. § 102(b) be withdrawn.

III. The Claims Are Clear And Definite

Claims 26-29 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Office Action incorrectly asserts that the term “oligonucleotide” is a relative term and that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicants respectfully request reconsideration of the rejection since the claims are clear and definite.

The term “oligonucleotide” is widely recognized and used by those skilled in the art for decades and refers to a polymer of nucleotides. Persons of ordinary skill would have no difficulty in determining whether a given polymer is an oligonucleotide. Accordingly, the claims are definite within the meaning of §112. *In re Mercier*, 185 U.S.P.Q. 774 (C.C.P.A. 1975) (claims sufficiently define an invention so long as one skilled in the art can determine what subject matter is or is not within the scope of the claims). Accordingly, Applicants respectfully request that the rejection of claims 26-29 under 35 U.S.C. § 112, second paragraph be withdrawn.

IV. The Claims Are Supported By Sufficient Written Description

Claims 26-29 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to provide sufficient written description of the claimed invention. The Office Action incorrectly asserts that the specification fails to provide sufficient written description for particular embodiments of the claimed invention. The Office Action concludes, albeit erroneously, that one skilled in the art would be required to resort to undue experimentation in order to practice the full scope of the claimed invention. Applicants traverse the rejection and respectfully request reconsideration thereof since

the specification provides sufficient written description and enables one skilled in the art to practice the claimed invention without being required to perform any amount of undue experimentation.

The Office Action asserts that Applicants' specification provides a sufficient written description of a 5'-UTR comprising a molecular interaction site that is present in RNA. The Office Action, however, incorrectly asserts that the specification does not provide a written description of i) an oligonucleotide that comprises a molecular interaction site that is present in RNA, ii) an oligonucleotide that comprises a molecular interaction site that is present in prokaryotic RNA, and iii) an oligonucleotide that comprises a molecular interaction site that is not present in eukaryotic or human RNA. The Office Action, apparently in support of the rejection, cites pages 32-44 of the specification.

As stated in the "Revised Interim Guidelines for Examination of Patent Applications Under the 35. U.S.C. Sec. 112, para. 1 'Written Description' Requirement,"

Possession may be shown by actual reduction to practice, by a clear depiction of the invention in detailed drawings which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention, or by a written description of the invention describing sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention.

In accordance with these standards, Applicants have indeed, provided a sufficient written description of the claimed inventions. First, as recognized in the Office Action, Applicants provide a detailed description of identification of a molecular interaction site in the 5'-UTR of ferritin which contains the iron responsive element. The entire nucleotide sequence of ferritin was used as a starting sequence. Indeed, Applicants need not provide an example of a molecular interaction site in every region of a gene in order to satisfy the written description requirement. In any event, Applicants also teach identification of molecular interaction sites in, for example, histone 3'-UTR (Example 3), vimentin 3'-UTR (Example 4), transferrin receptor 3'-UTR (Example 5), ornithine decarboxylase 3'-UTR (Example 6), interleukin 2 3'-UTR (Example 7) and interleukin 4 3'-UTR (Example 8). Further, Applicants teach in Table numerous additional examples of both 5'-UTRs and 3'-UTRs

which can be used to identify other molecular interaction sites. Thus, Applicants have provided a written description of the invention describing sufficient relevant identifying characteristics. Accordingly, the specification clearly provides sufficient written description of an oligonucleotide that comprises a molecular interaction site that is present in RNA.

No amount of undue experimentation is required to identify molecular interaction sites in prokaryotic RNA and make an oligonucleotide comprising the same. Indeed, one skilled in the art need only begin with a particular prokaryotic nucleotide sequence, as desired by the user, and perform the same steps for the eukaryotic RNA as described in detail in the specification. Further, no amount of undue experimentation is required in order identify molecular interaction sites that are prokaryotic RNA but not in human or eukaryotic RNA. As discussed in the specification at page 29, for molecular interaction sites in prokaryotes, one skilled in the art can discard human sequences, if found. Significantly, the Office Action is silent in regard to what undisclosed experimentation is deemed to be necessary in order to practice the claimed invention. In view of the foregoing, Applicants respectfully request reconsideration of the rejection since the specification provides sufficient written description of the claimed invention which requires no amount of undue experimentation to practice.

V. Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited.

Respectfully submitted,



Paul K. Legaard

Registration No. 38,534

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WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439